Appendix H. Evidence Tables and Overall Quality Ratings

Evidence Table H-1: Support

Evidence Table H-1a. Support trials

| **Author, year Country Overall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age**  **Sex**  **Race** | **Intervention Type** |
| --- | --- | --- | --- | --- | --- |
| Allman, 19871  US Good | 18 years or older Presence of a PU on sacrum, buttocks, trochanters, or back Activity expected to be limited to bed or chair in hospital for at least one week Patient expected to live at least one week | Previous inclusion in trial Skin graft or flap planned for pressure sore within one week | NR/140/72/65 | Age (Mean): 67 years  Female: 58%  Race: Black: 62% | Support: AF Beds |
| Branom, 20012 US Poor | Admitted as inpatient to one of the two test sites Stage III or IV PUs on trunk or pelvis Bedridden | NR | NR/NR/20/20 | Age (Mean):74 years  Female: NR  Race: NR | Support: Support: Air Bed with Foam Overlay |
| Caley, 19943 US Poor | Existing PU  LAL recommended for treatment by MD or enterostomal therapy nurse | NR | NR/NR/93/55  (106 PUs. Results presented for PUs) | Age (Mean): 76 years  Female: 60%  Race:  Caucasian: 87%  African American: 13% | Support: LAL Beds |
| Clark, 1997 4  UK Fair | Over 65 years old  Stage II, III, or IV PU greater than 2 cm2 in surface area  PU located on the sacrum or ischial tuberosities  At moderate to high risk of developing further sores Able to sit for at least 2 hours  Serum albumin level of greater than 2.5 mg/dl Expected to remain in study for more than 7 days | PU greater than 15 cm2 | NR/33/33/25 | Age (Mean): 83 years  Female: 72%  Race: NR | Support: AP Cushions |
| Day, 1993 5  US Poor | Hospitalized  18 years or older  Stage II, III or IV PU Life expectancy of at least one week Activity limited to bed or chair during hospitalization | Previous study enrollment Expected hospitalization less than 7 days Skin graft or flap within 7 days of enrollment. | 118/83/83/83 | Age (Mean):76 years  Female: 58%  Race: NR | Support: Air suspension |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age**  **Sex**  **Race** | **Intervention Type** |
| Devine, 19956 Scotland Fair | Patients admitted to Geriatric Unit  PU of Stage II or above (on a five grade scale) | NR | NR/NR/41/30 | Age (Mean): 83 years  Female: 59%  Race: NR | Support: AP Beds |
| Evans, 2000 7 Land, 20008  UK Good | 65 years or older  Stage III PU or stage II PU and one or more of the following: difficulty repositioning in bed and unable to tolerate at 30 degree tilt; unable to move in bed; in bed for more than 20 hours in 24 hours; weight greater than 108 kg and bed bound; or undergone spinal anesthetic | Spinal metastases  Exudating wounds that may lead to hygiene or infection control problems  Weight greater than 250 kg | NR/NR/32/32 | Age (Mean):81 years  Female: 78%  Race: NR | Support: AP Beds |
| Ferrell, 19939 US Good | Stage II or higher PU (Shea scale) on trunk, buttocks or trochanters | Expected survival of less than one month Previous participation in study Previous or planned surgical excision of PU. | NR/NR/84/84 | Age (Mean):85 years  Female: 50%  Race: NR | Support: LAL Beds |
| Groen, 199910 Holland Fair | 60 years or older PU on truck classified as grade III or IV  (article did describe grading system) | Severe or terminal illness | NR/NR/120/101 | Age (Mean): 83 years  Female: NR  Race: NR | Support: Foam and Water Mattresses |
| Izutsu, 199811 Japan Poor | Bedridden patients with decubitus | Immunocompromised and patients with mycobacterial infections | NR/NR/31/31 | Age (Mean): 78 years  Female: 58%  Race: NR | Support: Automatic Rolling Air Cushioned Bed |
| Jackson, 198812  US Poor | 18 years or older  Stage III, IV, or V PU  Required some form of pressure-relieving device | Renal disease; fluid restriction, dehydration, congestive heart failure/pulmonary edema; urinary incontinence (in which indwelling catheters were contraindicated) and severe diarrhea; daily treatments that required getting the patient into and out of the air-fluidized bed; patient inability to get into and out of bed without assistance; sensory deprivation; and poor ventilatory excursion. | NR/NR/35/35 | Age (Mean):77 years  Female: 64%  Race: NR | Support: AF Beds |
| Keogh, 200113 UK Poor | Patient over 18 years old  Patients had to give consent  Likely to stay in bed for at least 12 hours a day  Tissue damage no greater than stage I PU | Patient with terminal illness  Weighing more than 120 kg  Patients posing a manual handling risk who required an electric bed. | NR/100/100/70 (14 had PU on admission and were analyzed for treatment) | Age (Mean): 70 years  Female: 45%  Race: NR | Support: Profiling Bed |
| Makhsous, 200914 US Fair | Wheelchair user with SCI  Stage II or III PUs in sacral and/or ischial area Able to independently use manual or powered wheelchair Sitting tolerance of at least 4 hours per day | Degenerative disorders of the spine  History of injury or surgery of the pelvis, hip joint and the thigh; hip contractures Severe pain, spasm, and psychological concerns preventing proper cooperation | NR/NR/44/44 | Age (Mean):43 years  Female: 7%  Race: NR | Support: Cyclic Pressure Relief Seats |
| Malbrain, 201015 Belgium Fair | ICU patients with high PU risk (Norton Score ≤to 8) or a PU who were going to require mechanical ventilation for an estimated duration of at least 5 days. | If consent was not obtained from closest relative or at least one of each of the two mattresses studied were not available when the patient was admitted. | NR/NR/16/16 | Age (Mean): 64 years  Female: 50%  Race: NR | Support: Reactive Air and Active Alternating Pressure |
| Mulder, 199416 US Poor | PU Stage III or IV (Int'l Assoc. of Enterostomal Therapies) PU area between 1.5 cm x 1.5 cm and 10.0 cm x 20.0 cm | Carcinomatosis  Osteomyelitis affecting the target PU  Uncontrolled target PU infection  Immune deficiency disorders  Inadequate nutritional status | NR/NR/49/39 | Age (Mean): NR  Female: NR  Race: NR | Support: LAL Beds |
| Munro, 198917 US Fair | Stage II or III PU  Expected to remain in hospital at least 15 days | Stage IV PU  Weight over 250 pounds  Extremely malnourished (<70% of ideal body weight) or with serum albumin <2.1g /100 ml | NR/NR/40/40 | Age (Mean): 67  Female: 0%  Race: NR | Support: AF Bed |
| Nixon, 200618 UK Good | Sub group of large study of PU prevention and treatment  55 years old or older Admitted to participating vascular, orthopaedic, medical or geriatric ward in previous 24 hours Expected length of stay 7 or more days Consented to participate Restricted mobility or Stage II PU | Stage III or higher existing PU Prior participation in trial Elective surgery patients with planned post-op in ICU or admitted more than 4 days pre surgery Slept in chair at night Weight more than 140 kg or less than 45 kg | 6155/1972/1972/1971  Full trial including prevention.  NR/NR/113/113 for patients with PUs | Age (Mean):  75 years  Female: 64%  Race: NR | Support: AP Overlay and Mattresses |
| Rosenthal, 200319 US Poor | Stage III or IV PU on coccyx, trochanter, or ischial tuberosities  Able to sit up during previous 6 months with assistance  Alert | Previously enrolled in a trial to treat their current pressure PU; already using LAL or transfer to LAL was planned, skin grafting was planned within 1 week; they had an active sinus tract or fistula, nutrition was poor, as indicated by albumin levels below 3.0 g/dL; antibiotics were required to treat methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, or active skin infection; osteomyelitis was diagnosed; body weight was below 60 kg; patients were unable to flex both hip and knee past 90 degrees.   Further, persons with sacral PU were excluded from the study because the sacral area is suspended above the generic total contact seat and hence is not in contact with the seat. | NR/NR/207/203 | Age (Mean): 70 years  Female: NR  Race: NR | Support: Generic Total Contact Seat |
| Russell, 2000(a)20  Russell, 2000(b)21 UK Fair | Stage II or higher PU (Torrance grading scale) | Unwilling to participate  Randomized equipment not available  Previous inclusion in trial and readmitted  Weighed more than 25 stone | NR/NR/183/112 | Age (Mean): 84 years  Female: NR  Race: NR | Support: AP Beds |
| Russell, 200322 UK Fair | Admitted between April 2001 and April 2002 Stage I PU or above on EPUAP | Unwilling to participate  Previously in trial  Obese | NR/NR/199/158 | Age (Mean): 80 years  Female: 54%  Race: NR | Support: AP vs. Fluid Overlay |
| Strauss, 199123 US Fair | 16 years or older  Stage 3 or 4 PU Future PU-related hospitalization expected  Severely limited mobility  Adequate social support to use home AF therapy  Likely to live one year or more;  Out of hospital at least 3 weeks; Medical provider willing to closely manage care in home | Febrile or septic or otherwise required immediate hospitalization  PU on radiated skin | NR/112/97/69 | Age (mean): 64 years  Female: 49%  Race: NR | Support: AF Beds |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)** | **Treatment A** | **Treatment B** | **Treatment C** | **Outcomes: Complete Wound Healing** | **Outcomes: Wound Surface Area** | **Outcomes: Healing Time** | **Outcomes: Pain** |
| Allman, 19871 US Good | Stage I, II, III, IV, and unstageable  Treatment A:  Superficial-Epidermis: 13% (4) Superficial- Dermis: 39% (12) Deep-Subcutis: 29% (9) Deep-Bone/Muscle: 6% (2) Deep-Eschar: 13% (4)  Treatment B:  Superficial-Epidermis: 12% (4) Superficial- Dermis: 47% (16) Deep-Subcutis: 32% (11) Deep-Bone/Muscle: 3% (1) Deep-Eschar: 6% (2) | AF bed with positioning every 4 hours from 0700 hours to 2300 hours. | Alternating air mattress covered by a foam pad with repositioning every 2 hours and elbow or heel pads as needed. | NA | Patients with one or more healed sores during study  Treatment A: 65% (20) Treatment B: 44% (15) p=0.10 | Change in total surface area, cm2 Median (Range) Treatment A: -1.2 (-38.0 to +15.5) Treatment B: + 0.5 (-55.1 to +94.7) p=0.01  50% reduction in total surface area Treatment A: 29% (9) Treatment B: 24% (8) p=0.64 | NR | Change in pain intensity from baseline  Treatment A:  Decreased: 62% (8)  No change: 38% (5)  Increased: 0  Treatment B:  Decreased: 29% (4) No change: 50 (7) Increased: 21% (3)  p=0.01  Change in comfort from baseline  Treatment A Increased: 62% (8)  No change: 31% (4)  Decreased: 8% (1)  Treatment B:  Increased: 23% (3) No change: 31% (4) Decreased: 46% (6)  p=0.04 |
| Branom, 20012 US Poor | Treatment A: Stage III: 30% (3) Stage IV: 70% (7)    Treatment B:  Stage III: 25% (2) Stage IV: 75% (6)  Staging system not cited | Non-powered air mattress with foam overlay | LAL mattress | NA | NR | At 3 Weeks Treatment A:  Mean Amount Closed (cm2): 17.0,  Mean % Closed: 43%  Treatment B:  Mean Amount Closed (cm2): 17.1,  Mean % Closed: 22%  At 8 Weeks Treatment A:  Mean Amount Closed (cm2): 25.8  Mean % Closed: 60%  Treatment B:  Mean Amount Closed (cm2):  22.2  Mean % Closed: 40% | At 3 Weeks  Treatment A:  Rate of Closure per Week (cm2): 5.7  % Closed per Week: 14.4%  Treatment B:  Rate of Closure per Week (cm2): 5.7  % Closed per Week: 7.2%  At 8 Weeks  Treatment A:  Rate of Closure per Week (cm2): 3.5  % Closed per Week: 9.0%  Treatment B:  Rate of Closure per Week (cm2): 2.8  % Closed per Week: 5.0% | NR |
| Caley, 19943 US Poor | NR | LAL Bed | LAL overlay | NA | NR | Change in Surface Area Mean, cm2  Treatment A: 3.8  Treatment B: 10.2   p=0.06   Perimeter average of initial and final, cm Mean (Range) Treatment A: 20.0  Treatment B: 23.7   p=0.06 | NR | NR |
| Clark, 19974 UK Fair | Treatment A:  Stage II: 50% (7) Stage III: 14% (2) Stage IV: 36% (5)  Sacrum: 93% (13)  Ischial: 7% (1)  Treatment B:  Stage II: 64% (7) Stage III: 9% (1) Stage IV: 27% (3)  Sacrum: 91% (10)  Ischial: 9% (1) | AP cushion with 4 cells | Static air filled cushion | NA | Treatment A: 21% (3) Treatment B: 45% (5)  p=NS | Mean Reduction in Area per Day(Stage II only) absolute change: mean  Treatment A: 0.13  Treatment B: 0.27 | NR | NR |
| Day, 19935  US Poor | Treatment A:  Stage II: 57% (25) Stage III: 14% (6) Stage IV: 25% (11) Unstageable: 5% (2)  Treatment B:  Stage II: 59% (23) Stage III: 21% (8) Stage IV: 10% (4) Unstageable: 10% (4) | Air-suspension bed | Foam overlay | NA | NR | Initial/ Ending Mean Area in cm2 by Stage  Stage II Treatment A: 12.7 /7.3  Treatment B: 10.0/5.3  Stage III and IV Treatment A: 51.8/37.1 Treatment B: 13.7/12.4  p>0.05 | NR | NR |
| Devine, 19956  Scotland Fair | Median Initial Stage, range Treatment A: 3 (2-5) Treatment B: 3 (2-5) Location (total population):  Sacrum/buttocks: 59%  Heels: 20%  Trochanter: 17%  Others: 5% | AP bed | Airwave bed | NA | Treatment A: 64% (10)  Treatment B: 36% (5)  p=NS | Median Reduction per Day cm2 Treatment A: 0.089 Treatment B: 0.107  p=0.92 | NR | NR |
| Evans, 20007  Land, 20008 UK Good | Hospital  Treatment A:  Stage II: 43% (3)  Stage III: 57% (4)  Sacrum: 47% (4)  Buttock: 0  Heel: 53% (3)  Treatment B:  Stage II: 40% (2)  Stage III: 60% (3)  Sacrum: 40% (2)  Buttock: 20% (1)  Heel: 40% (2)  Nursing Home  Treatment A:  Stage II: 10% (1)  Stage III: 70% (7)  Stage IV: 20% (2)  Sacrum: 20% (2)  Buttock: 10% (1)  Heel: 60% (6)  Malleolus: 10% (1)  Treatment B:  Stage II: 20% (2)  Stage III: 40% (4)  Stage IV: 40% (4)  Sacrum: 50% (5)  Buttock: 0  Heel: 40% (4)  Malleolus: 10% (1) | AP mattress | Other brands of AP mattresses | NA | NR | Median Reduction per Day (range)  Hospital,  Treatment A: 0.12 cm2 (0-0.21cm2) Treatment B: 0.08cm2 (0.04-0.33cm2) p=NS  Nursing Home  Treatment A: 0.11 cm2 (0.04-0.41cm2) Treatment B: 0.05cm2 (0-0.48cm2) p=NS  Median Relative % reduction per Day (range) Hospital  Treatment A: 2.44% (0-7.14%) Treatment B: 1.34% (1.11-2.88%) p=NS  Nursing Home Treatment A: 1.57% (0.45-5.00%) Treatment B: 0.99% (0-2.54%) p=NS | NR | NR |
| Ferrell, 19939 US Good | Stage (Shea scale)  Treatment A:  Stage II: 58% (25)  Stage III/IV: 42% (18)  Treatment B:  Stage 2: 66% (27)  Stage III/IV: 34% (14)  Deep Ulcers | LAL Bed | Foam convoluted mattress (10 cm) overlying a hospital mattress. | NA | Treatment A: 60% (26) Treatment B: 46% (19)  p=0.19 | Decrease in Size, mm2 per Day Median (25th, 75th percentile)   All PUs Treatment A: 9.0 (4.0, 19.8)  Treatment B: 2.5 (0.5, 6.5)  p=0.0002 | NR | NR |
| Groen, 199910 Holland Fair | Stage III or IV was an inclusion criteria | High Quality Foam Replacement Mattress | Water mattress | NA | Percent completely healed at four weeks A. Treatment A: 45% B. Treatment B: 48%  p=NS | NR | NR | Reported as complicating factor: see harms |
| Izutsu, 199811 Japan Poor | Average Grade:  Treatment A: II  Treatment B: III | Rolling air cushion bed | Conventional bed with their positions being changed every 2 hours | NA | NR | Wound Area Reduction: No significant difference (p=NR) | NR | NR |
| Jackson, 198812 US Poor | NR | Air-Fluidized mattress | A variety of non air-fluidized devices were used, including a non alternating air mattress | NA | NR | Patients Experiencing Decrease in Ulcer Area:  Treatment A: 60% (9)  Treatment B 45% (9).  p=NR | NR | NR |
| Keogh, 200113 UK Poor | Treatment A: Stage I: 11.4% (4)  Treatment B:  Stage I: 28.5% (10) | Profiling Bed | Conventional Bed | NA | Treatment A:  100% (4)  Treatment B: 20% (2)  p=NR | NR | NR | NR |
| Makhsous, 200914 US Fair | Treatment A:  Stage II: 55% (12)  Stage III: 45% (10)  Treatment B:  Stage II: 43% (9)  Stage III: 57% (13) | Wheelchairs with a cyclic pressure-relief seating system | Regular wheelchairs | NA | NR | Reduction in Wound Area: Treatment A: 45% Treatment B: 10%  p<0.001  Probability to achieve 30% wound closure at 30 days: Treatment A: 0.727 Treatment B: 0.364 p=0.007 | Median Time 30% Wound Reduction in Days Treatment A: 25 Treatment B: >30  p=0.007 | NR |
| Malbrain, 201015 Belgium  Fair | PU at admission.  Treatment A:  Category I: 50% (5)  Category II: 30% (3)  Category III: 20% (2)  Treatment B:  Category I: 20% (2)  Category II: 20% (2)  Category III: 0 | AP mattress (Nimbus 3) | Reactive low-pressure mattress | NA | NR | Change in surface area (cm2)  Treatment A:-2.1  Treatment B: 25.8  p=0.05 | NR | NR |
| Mulder, 199416 US Poor | Treatment A:  Stage III: 77% (24)Stage IV: 23% (7)  Sacral: 48% (15)  Trochanter: 29% (9)  Ischial: 16% (5)  Heel: 3% (1)  Ankle: 3% (1)  Treatment B:  Stage III: 72% (13)  Stage IV: 28% (5)  Sacral: 50% (9)  Trochanter: 28% (5)  Ischial: 22% (4)  Heel: 0  Ankle: 0  (International Association of Enterostomal Therapists staging system) | LAL Bed | Foam Overlay | NA | Treatment A: 16% (5) in treatment B: 17% (3)  p=NR | Decrease in ulcer area was 77% greater in treatment A vs. treatment B  p=0.042 | NR | NR |
| Munro, 198917 US Fair | Total Population:  Stage II: 52% (21)  Stage III: 48% (19) | Air fluidized bed | Standard hospital bed | NA | NR | Mean ulcer size shrank in treatment A and expanded in treatment B.  p=0.05 | NR | Pain scores fell over time in treatment A and Treatment B:  p=0.359 |
| Nixon, 200618 UK Good | Stage II Only | AP Mattress Overlay | AP Mattress Replacement | NA | Treatment A: 34% (20)  Treatment B: 35% (19) | Mean Absolute change  Treatment A: 1.0  Treatment B: 2.0   Mean Percentage change  Treatment A: -35  Treatment B: 34.4 | Median Time to Healing:  Treatment A: 20 days  Treatment B: 20 days  p=0.86 | NR |
| Rosenthal, 200319 US Poor | Stage III and IV | Generic Total Contact Seat | LAL Bed | Bed Overlay | NR | NR | Median Time to Total Healing: Treatment A: 3.33 months  Treatment B: 4.38 months  Treatment C: 4.55 months | NR |
| Russell 2000(a)20 Russell 2000(b)21 UK Fair | Average Ulcer Severity   Treatment A: 2.46  Treatment B: 2.57 | AP Bed and Cushion (Nimbus 3 and Aura Cushion) | AP Bed and Cushion (Pegasus Cairewave and Proactive Seating cushion) | NA | NR | Mean Linear Growth Rate of Wound Edge (area change/ circumference/ time increment) (mm/24 hours): Treatment A: Stage IIa: 1.50 Stage IIb: 0.04 Stage III +: excluded due to insufficient data  Treatment B: Stage IIa 0.17 Stage IIb -0.84 Stage III +: excluded due to insufficient data  p=NS | NR | NR |
| Russell, 200322 UK Fair | NR | AP mattress | Fluid overlay system | NA | NR | NR | NR | NR |
| Strauss, 199123 US Fair | Stage III and IV | AF Bed | Conventional treatment. Included AP beds, air, water and high density foam. | NA | Treatment A: 62% (29) healed to Stage 2 or better and were removed from treatment  Treatment B: NR | NR | Mean Days to Heal to Stage II or Better: Treatment A: 93  Treatment B:  NR | NR |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Outcomes: Infection Rate** | **Outcomes: Osteomyelitis** | **Outcomes: Recurrence Rate** | **Other Outcomes: Specify** | **Timing: Duration of Followup** | **Setting** |
| Allman, 19871 US Good | NR | NR | NR | Patients who Improved: Treatment A: 62% Treatment B: 29%  p=0.05  Odds of improvement on Treatment A compared to Treatment B:  5.6 | Weekly from enrollment until death or discharge from hospital Median: 13 days Range: 4 to 77 days | Hospital |
| Branom, 20012  US Poor | NR | NR | NR | Goals for Treatment vs. Results (at admission goal was classified as progressive closure, prepare for flap or maintenance)  Treatment A vs. LAL  Achieved: 70% (7) Exceeded: 30% (3) Not achieved: 0%  Treatment B:  Achieved: 50% (4) Exceeded: 13% (1) Not achieved: 37% (3) | 8 weeks | Acute care with specialty in ventilator and sub-acute center |
| Caley, 19943 US Poor | NR | NR | NR | NR | 1 month or until hospital discharge. | Hospital |
| Clark, 19974  UK Fair | NR | NR | NR | Stage III and IV only  Mean Change in Volume (cm3): Treatment A:  0.56  Treatment B: 0.49  % Change in Volume per Day: Treatment A: 1%  Treatment B: 0.7% | Mean Days of Followup Treatment A: 58.64  Treatment B: 43.73  p=NS | Hospital and nursing homes |
| Day, 19935  US Poor | NR | NR | NR | Mean of Weekly Patient Assessments of Comfort  Treatment A: 4.1 Treatment B: 3.7 p>0.05  Note: most patients unable to report | Assessed weekly until discharge. | Hospital |
| Devine, 19956 Scotland Fair | NR | NR | NR | Median, range (10 point scale)  How comfortable was the mattress? Treatment A: 8 (5-10) Treatment B: 8 ( 3-10)  How well did you sleep? Treatment A: 8 ( 4-10) Treatment B: 8(7-10)  Many patients unable to report | Followed for 4 weeks after enrollment. | Nursing home/Long-term care |
| Evans, 20007 Land, 20008 UK Good | NR | NR | NR | Median weekly comfort rating (5 point scale)  Hospital: Treatment A: 5 Treatment B: 4 p=0.006  Nursing Home: Treatment A: 5 Treatment B: 4 p=0.002 | Hospital: Until death, discharge, or healing  Nursing Home:  Until death, hospitalization, healing, or completion of study period. | Hospital and nursing home |
| Ferrell, 19939 US Good | NR | NR | NR | Improvement  Change in Stages Median (25th, 75th percentile)  Shea scale Treatment A: 2.0 (0, 2) Treatment B: 1.0 (0,2) p<0.05  Sessing scale Median (25th, 75th percentile)  Treatment A: 3.0 (1,3) Treatment B: 1.0 (0,3) p<0.01  Cure Probability ratio= Cox hazard ratio (probability of cure with Low-Air Loss divided by the probability of cure with foam for subjects under each condition for the same period of time. Ratio (95% confidence level) p value All PU 2.66 (1.34-5.17) p=0.004 Superficial 2.60 (1.24-5.41) p=0.01 Deep 2.97 (0.61-14.5 p=0.18 | Until healing, death, transfer, withdrawal, or protocol deviation  Number of Followup Days, Median (25th, 75th percentile): Treatment A: 33 (15, 60) Treatment B: 40 (21.5, 90.5) p=0.56 | Nursing home/LTC |
| Groen, 199910  Holland Fair | NR | NR | NR | NR | Four weeks from initial assessment and assignment | Nursing home/LTC |
| Izutsu, 199811  Japan Poor | NR | NR | NR | Improvement in Stage Treatment A: Stage improved from 2.8 to 2.0 p<0.01 after three months  Treatment B: Stage changed from 3.0 to 3.2 p>0.5 after three months. | 3 months | Nursing home/LTC |
| Jackson, 198812  US Poor | NR | NR | NR | NR | Until discharge  Median Days in Study:  Treatment A: 20 days  Treatment B: 37.5 days | Hospital |
| Keogh, 200113 UK Poor | NR | NR | NR | NR | 5 to 10 days. | Hospital |
| Makhsous, 200914 US Fair | NR | NR | NR | Percentage Improvement in PUSH score (mean): Treatment A: 21.9  Treatment B: 5.8 (9.2) p=0.003 | 30 days | Community |
| Malbrain, 201015 Belgium Fair | NR | NR | NR | Change in PUSH score –Treatment A: 1  Treatment B; 3.4  p=0.01  Change in Category (EPUAP)  Treatment A: 0  Treatment B: 0.8  p=0.03 | Followed until discharge. Mean was 11days | Hospital |
| Mulder, 199416  US Poor | NR | NR | NR | NR | 12 weeks or until ulcer healed | Nursing home/Long-term care |
| Munro, 198917 US Fair | NR | NR | NR | NR | 15 days | Hospital |
| Nixon, 200618 UK Good | NR | NR | NR | NR | Until healing, discharge, or end of trial. | Hospital |
| Rosenthal, 200319 US Poor | NR | NR | NR | NR | 6 months | Nursing home/Long-term care |
| Russell, 2000(a)20  Russell, 2000(b)21 UK  Fair | NR | NR | NR | NR | Until discharge or healing | Hospital |
| Russell, 200322 UK Fair | NR | NR | NR | Overall Ulcer Progress:  Treatment A:  Improved: 71% (60)  No Change: 1% (1)  Worse: 27% (22)  Treatment B:  Improved: 75% (56) No change: 4% (3) Worse: 21% (16) p=0.67  Worst Ulcer Progress:  Treatment A:  Improved: 76% (63)  No Change: 1% (1)  Worse: 23% (19)  Treatment B:  Improved: 84% (63) No change: 5% (4) Worse: 11% (8) p=0.053 | Until discharge  Average Length of Stay: Treatment A: 22.17 days Treatment B: 20.05 days. p=0.23 | Hospital |
| Strauss, 199123 US Fair | NR | NR | 11% (5) returned to AF bed after recurrence of stage 3 or 4 PU | Improved Reviewer 1 % (#)/ Reviewer 2 %/(#) Treatment A:91% (20) /82% (18) Treatment B: 62% (8)/77% (10)  AF had 55% fewer hospital days and used fewer inpatient resources. | 36 weeks | Other |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Harms: Pain** | **Harms: Dermatologic Complication** | **Harms: Bleeding** | **Harms: Infection** | **Severe Adverse Events** | **Withdrawal due to Adverse Events** | **Overall Adverse Events Rate** | **Funding Source** |
| Allman, 19871 US Good | NR | New skin breakdown  Treatment A 29%:(9) Treatment B: 44% (15) p=0.24 | Treatment A:  Epitaxis: 3% (1) | NR | NR | 4 withdrew due to difficulty in transferring from AF beds | 3% | Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs-Wellcome Scholar in Pharmacoepidemiology. |
| Branom, 20012 US Poor | NR | NR | NR | NR | NR | NR | NR | Mattress supplied by Span-America Medical System |
| Caley, 19943 US Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Clark, 19974 UK. Fair | NR | NR | NR | NR | NR | 2 (1 from each group) withdrew due to malfunction of the cushion | NR | Raymor Ltd. supplied Quadtro cushions. Funding by Pegasus Airwave Ltd. |
| Day, 19935 US Poor | NR | NR | NR | NR | NR | NR | NR | Supported in part by funding from KCI |
| Devine, 19956  Scotland Fair | NR | NR | NR | NR | NR | NR | NR | Supported by HNE healthcare grant for a part-time research nurse and provision of 3 Nimbus 1 mattresses |
| Evans, 20007 Land, 20008 UK Good | NR | NR | NR | NR | NR | NR | NR | Huntleigh Healthcare |
| Ferrell, 19939 US Good | NR | NR | NR | NR | NR | Treatment B: 9 subjects were deviated from the protocol because their ulcers became substantially worse or failed to heal. | NR | Jewish Home for the Aged of Greater Los Angeles Sepulveda VA Geriatric Research and Education Clinical Center West Los Angeles VA Geriatric Research and Education Clinical Center; Kinetic Concepts International |
| Groen, 199910  Holland Fair | Patients with Pain Treatment A: Week 0: 40% Week 1: 27% Week 2: 22% Week 3: 10% Week 4: 4%  Treatment B:  Week 0: 20% Week 1: 17% Week 2: 12% Week 3: 5% Week 4: 4% | Patients with Eczema  Treatment A:  Week 0: 10% Week 1: 0% Week 2: 2% Week 3: 4% Week 4: 0%  Treatment B: Week 0: 2% Week 1: 0% Week 2: 0% Week 3: 0% Week 4: 0%  p=NS  Maceration Treatment A:  Week 0: 17% Week 1: 15%.0 Week 2: 7% Week 3: 6% Week 4: 4% Treatment B:  Week 0: 13% Week 1: 8% Week 2: 2% Week 3: 4% Week 4: 4%  p=NS | NR | NR | NR | NR | NR | NR |
| Izutsu, 199811 Japan  Poor | NR | NR | NR | NR | NR | None | NR | NR |
| Jackson, 198812 US Poor | NR | NR | Among the 15 patients in the treatment group, all had some granulation or bleeding at both entry and endpoint. Among 17 patients in the comparator group with evolutions at both entry and endpoint, 14 continued to have granulation or bleeding. In one subject, granulation or bleeding ceased; in two subjects, granulation or bleeding developed. These findings were not statistically significant. | NR | NR | NR | NR | Support Systems International |
| Keogh, 200113 UK Poor | NR | NR | NR | NR | NR | NR | NR | Huntleigh Healthcare Ltd |
| Makhsous, 200914 US  Fair | NR | NR | NR | NR | NR | NR | NR | National Institutes of Health and Falk Medical Research Trust |
| Malbrain, 201015 Belgium Fair | NR | NR | NR | NR | NR | None | NR | Beds, but no other support provided by manufacturers. No other funding source reported. |
| Mulder, 199416 US Poor | NR | NR | NR | NR | NR | NR | NR | Kinetic Concepts, Inc. |
| Munro, 198917  US Fair | NR | NR | NR | NR | NR | NR | NR | Support Systems International |
| Nixon, 200618 UK Good | NR | NR | NR | NR | NR | NR | Nine reported for the full trial, but not separated for the cohort with existing PU. These included 4 falls, 3 cot-side incidents, one contact dermatitis and one patient who caught back on bed rail when mattress deflated during transfer. | National Health Service, Health Technology Assessment |
| Rosenthal, 200319 US.  Poor | NR | NR | NR | NR | NR | 3 patients worsened on bed overlay and were withdrawn. | NR | Equipment loaned to hospital by manufacturers. |
| Russell, 2000(a)20  Russell, 2000(b)21 US Fair | NR | NR | NR | NR | NR | NR | NR | Equipment loaned to hospital by manufacturers |
| Russell, 200322 UK Fair | NR | NR | NR | NR | NR | NR | NR | KCI Medical |
| Strauss, 199123  US Fair | NR | Treatment A:  Dry skin: "several"; number NR  Dehydration: 1 | NR | NR | NR | NR | NR | Support Systems International |

Note: AF=air fluidized, AP=alternating pressure, LAL= low air loss.